

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

W. R. GRACE & CO.-CONN.,

Plaintiff,

C.A. No. 20-1098-CFC

V.

ELYSIUM HEALTH, INC.,

Defendant.

**ELYSIUM’S OPPOSITION TO
PLAINTIFF’S MOTION TO DISMISS DEFENDANT’S
INEQUITABLE CONDUCT COUNTERCLAIMS AND STRIKE
RELATED AFFIRMATIVE DEFENSES**

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Dated: June 13, 2022

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Defendant Elysium Health, Inc. respectfully submits this opposition to Plaintiff W.R. Grace & Co. Conn.'s Motion to Dismiss (D.I. 113).

Elysium understands the seriousness of inequitable conduct allegations and does not bring them lightly. Grace sold crystalline nicotinamide riboside chloride ("NR-Cl") for more than a year before it applied for¹ and obtained patents directed to the crystalline Forms it sold. Grace's identified employees intentionally withheld this material information from the PTO to obtain patent claims that would not have issued otherwise, and did so to sue Elysium. That is why Elysium makes these serious allegations.

Grace incorrectly asserts that Elysium: (1) failed to plead "but-for materiality," (2) failed to plead the "requisite knowledge and intent," and (3) has not established that Grace "destroyed evidence" (not an inequitable conduct element); each ignores Elysium's actual allegations and sidesteps the blackletter law that allegations must be taken as true for purposes of this motion.

For instance, Elysium did set forth the materiality of Grace's misconduct. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹ For this motion only, Elysium treats provisional applications as the relevant dates.

[REDACTED]

[REDACTED]

Elysium also provides specific evidence showing that seven individuals knowingly intended to mislead the PTO despite a duty to disclose material information. Rule 9(b) makes clear that intent need only be pleaded generally, but Elysium goes beyond this requirement, showing facts from which one can reasonably infer that reasonably imply Grace employees intentionally concealed material information to placate Grace's sole NR-CI customer, ChromaDex.

For instance, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Grace also incorrectly states that Elysium failed to show that the seven named individuals had knowledge of invalidating offers/sales. But, as Elysium details, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Grace also sets up a strawman to knockdown – resulting in sample degradation over the last decade. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Grace does so, so it does not need to address Elysium’s actual pleading. Grace’s motion is essentially for summary judgment, arguing evidentiary burdens instead of acknowledging that under R.9 Elysium’s factual allegations must be taken as true for purposes of its motion. The issue is sufficiency of Elysium’s pleading – not a summary judgment-type analysis (although Elysium provided evidence well-beyond mere allegations). Elysium, at this stage, need only plead facts supporting a reasonable inference that Grace’s seven employees engaged in inequitable conduct. Elysium has done so.

Grace's motion should be denied.

I. BACKGROUND

The facts most pertinent to the pending motion are restated briefly. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

That is inequitable conduct.

II. LEGAL STANDARDS

A. Motion to Dismiss

Grace's Fed.R.Civ.P.12(b)(6) motion requires the Court accept as true all material allegations of the pleading. *Southco, Inc. v. Penn Eng'g & Mfg. Corp.*, 768 F. Supp. 2d 715, 719 (D. Del. 2011) (citation omitted). "The issue ... is not whether a [claimant] will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Id.* (citation omitted). If a pleading

“contain[s] sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face,’” dismissal must be denied. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citation omitted). Thus, Grace must show that “accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable” Elysium “is not entitled to relief.” *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d. Cir. 2000).

B. Pleading Inequitable Conduct

Federal Circuit law governs the sufficiency of inequitable conduct pleadings. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). “[A] party must state with particularity the circumstances constituting fraud or mistake” while “[m]alice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” Fed.R.Civ.P.9(b). R.9(b) is intended to provide “notice of the precise nature of the claim,” not test “factual allegations.” *Southco*, 768 F.Supp.2d at 720.

Inequitable conduct has two elements: (1) individual(s) associated with patent application filing/prosecution affirmatively misrepresented, failed to disclose, or submitted false material information to the PTO; and (2) did so with specific intent to deceive. *Exergen*, 575 F.3d at 1327 n.3. Pleading materiality requires “the specific who, what, when, where, and how of the material misrepresentation or omission.” *Id.* at 1327.

Intent requires the pleader “allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind.” *Id.* The pleading must include facts “giv[ing] rise to a reasonable inference of scienter, including both (1) knowledge of the withheld material information or of the falsity of the material misrepresentation, and (2) specific intent to deceive the PTO.” *Id.* at 1330. At the pleading stage, the proponent need only provide facts supporting a reasonable inference – “one that is plausible and that flows logically from the facts alleged” – that specific individual(s) knew and had the specific intent to deceive the PTO. *Id.* at 1328-29 & n.5.

Elysium’s pleading more than meets this standard for alleging inequitable conduct by Grace’s named employees.

III. ARGUMENT

A. Elysium Has Properly Pleaded Inequitable Conduct

Grace attempts to conflate *Therasense*’s evidentiary analysis with *Exergen*’s pleading standard, to impose an unreasonable pleading bar for allegations of inequitable conduct. D.I. 137 at 4-7; *cf. Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290-91 (Fed. Cir. 2011). *Therasense* addresses proving intent at trial, it did not disturb the pleading standard or require a party satisfy that burden of proof at the pleading stage. *See Wyeth Holdings Corp. v. Sandoz, Inc.*,

No. 09-955-LPS-CJB, 2012 U.S. Dist. LEXIS 26912, at *23-26 (D. Del. Feb. 3, 2012).

Accordingly, Elysium's pleading need only set out facts that, when taken as true, make the claim "plausible on its face." *Iqbal*, 129 S. Ct. at 1949. That means only pleading facts that make it plausible these individuals violated the duty of disclosure by making a material omission with intent to deceive the PTO. *Exergen*, 575 F.3d at 1327 n.3 (citation omitted). Elysium has done this.

B. Elysium Has Sufficiently Pleaded Materiality.

Elysium alleges the PTO would not have allowed claims for crystalline Forms I/II of NR-Cl had Grace disclosed its pre-critical date offers/sales of crystalline NR-Cl and that the issued claims are invalid under §102. D.I. 113 ¶¶44-94. In doing so, Elysium has provided the *who, what, where, when, and how* of this material omission. *Exergen*, 575 F.3d at 1328.

Who. Elysium's pleading identifies individuals by name, including [1] inventor Erik Carlson, [2-4] the other inventors (Messrs. Standen, Morrill and Osuna), [5] Brett Reynolds, Grace's Global Business Director, [REDACTED]

[REDACTED]. D.I. 113 ¶¶45, 67-70. These individuals, Elysium alleges, knowingly participated in violating the duty of disclosure.

What & Where. Elysium identified all asserted claims in its inequitable conduct charge: each claims a crystalline “Form” of NR-C1. *Id.* ¶50. Elysium’s pleading also provides examples of Grace’s invalidating offers to sell/sales,

[REDACTED]

The inventors of the Asserted Patents (*Id.* ¶¶16-17, 45)

[REDACTED] *Id.* ¶55.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

When. Elysium provided dates, with evidence, showing pre-critical date invaliding offers/sales, and associated ChormaDex purchase orders and ChromaDex resales. *Id.* ¶¶56-65, 78, 84, 90 & Exs. 3-4.

How. Elysium’s pleading describes how and why these pre-critical acts are “but for” material. [REDACTED]

[REDACTED]

[REDACTED]. *Id.* ¶¶58, 63. [REDACTED]

[REDACTED]

[REDACTED]. *Id.* ¶¶57, 62. In other words, Grace offered/sold the claimed Forms.

Elysium’s pleading sets out the framework an Examiner would use to react if she knew Grace previously offered/sold crystalline NR-Cl [REDACTED]

[REDACTED]. The examiner would have found the claims unpatentable, not allowing – *i.e.* rejecting – them. *Id.* ¶¶73, 76.

As alleged, Grace’s crystalline NR-Cl was ready for patenting when it offered/sold crystalline NR-Cl. *Id.* ¶¶57-65. The specific facts and circumstances

alleged show that these pre-critical date actions were commercial, not experimental in nature. *Id.* ¶¶60, 64-65.

When Elysium’s allegations are taken as true and viewed “in the light most favorable to [Elysium],” as they must, Elysium “state[s] a claim to relief that is plausible on its face.” *Iqbal* 129 S.Ct. at 1949; *Maio*, 221 F.3d at 481-82. *See Pollin Patent Licensing, LLC v. Capital One Auto Fin., Inc.*, No. 1:10-CV-07420, 2011 U.S. Dist. LEXIS 124805, at *11 (N.D. Ill. Oct. 25, 2011) (“As long as materiality is adequately alleged, the Court need not examine whether materiality can be proved”); *Aerocrine AB v. Apieron Inc.*, Civ. No. 08-787-LPS, 2010 U.S. Dist. LEXIS 31176, at 37 (D. Del. Mar. 30, 2010) (accord). Grace’s motion must be denied.

1. Elysium Pleads Facts That Show Claimed Crystalline Forms Were Offered/Sold Pre-Critical Date

Grace argues Elysium does not allege Grace offered/sold the claimed crystal forms – but Elysium did, with citations. D.I. 137, 6 (“Elysium pleads no facts showing that the claimed crystalline forms were sold.”). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As even

Grace's case citation makes clear, when it comes to crystal forms materiality can be established by evidence of the "*method to produce it.*" *UFCW v. Novartis Pharms. Corp.*, No. 15-CV-12732, 2017 U.S. Dist. LEXIS 102389, at *44 (D. Mass. June 30, 2017).²

Elysium's pleading includes that Grace's pre-critical dates NR-C1 was [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Pre-critical date documents, from January-February 2013 (D.I. 113, Ex. 2), prove this point. *E.g.*:

[REDACTED]

[REDACTED]

[REDACTED]

² While the facts Elysium recited are sufficient to state a claim, Elysium anticipates adducing additional evidence of materiality and intent as discovery of Grace and third-party ChromaDex continue.

Grace attempts to dismiss Elysium’s allegations concerning Grace’s [REDACTED] arguing those are “unwarranted inferences or self-evidently false assertions that the Court need not – and should not – accept as true.” D.I. 137 at 9. But, at the pleading stage “the court **must accept all well-pleaded factual allegations** ... as true **and draw all reasonable inferences** in favor of the [non-movant].” *Genentech, Inc. v. Amgen Inc.*, No. 17-1407- CFC, 2020 U.S. Dist. LEXIS 23311, at *7-8 (D. Del. Feb. 11, 2020) (citation omitted).

As set out in Elysium’s pleading, Grace made

This is undisputed.

³ Any color inconsistencies are beside the point, as Grace's own brief recognizes. See D.I. 137, 3. [REDACTED]

In making its motion, however, Grace made arguments it knows are incorrect. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

As Elysium pled, pre- critical dates Grace offered/sold [REDACTED]

[REDACTED]

[REDACTED] This is material to patentability.

2. Elysium Tied Its Allegations to the Asserted Claims

Grace wrongly asserts Elysium did not tie its allegations to claims or limitations. D.I. 137 at 12. Elysium's allegations are tied to the Form I and II limitations of each asserted claim, as construed by the Court. *E.g.* D.I. 113 ¶¶50

(“The *asserted claims of each of the Asserted Patents* recites or incorporates a crystalline ‘Form’ ...”), 48, 80, 86, 92.

The inequitable conduct goes to *all claims*, and, as other courts have observed, where inequitable conduct touches limitations common to all asserted claims, the party averring inequitable conduct does not need to identify the specific claim or subset of claims that are the subject of allegations. *Quest Integrity USA, LLC v. Clean Harbors Indus. Servs.*, No. 14-1482-SLR, 2015 U.S. Dist. LEXIS 95148, at *11-13 (D. Del. July 22, 2015) (assertions “that materially applies broadly to all claims” because the “invention ...had been sold before the bar date” sufficient, “at motion to dismiss stage of litigation.”); *Sysmex Corp., v. Beckman Coulter, Inc.*, No. 19-1642-JFB-CJB, 2022 U.S. Dist. LEXIS 86635, at *7 (D. Del. May 6, 2022) (recommending denial of inequitable conduct SJ noting that “asserted patents” generally claim “sample analyzers having a plurality of detectors...”).

Elysium’s allegations go to the claimed Forms, and that requirement is common to and what separates the three independent claims from the prior art.⁴ All other claims depend from these three independent claims, and therefore include this limitation. Thus, Elysium’s pleading correctly identifies the withheld

⁴ Independent claim 1 of the ’207 Patent adds XRD values. However, for purposes of this motion Elysium presumes *arguendo* otherwise patentable claims over prior art NR-CI literature, but-for Grace’s own actions.

information was “material to the patentability of the asserted claims” and ties them to all claims in suit, as cited above.

3. Elysium Applied the Correct Legal Standard

As recently reiterated, “the standard for establishing but-for materiality in the inequitable conduct context only requires a preponderance of the evidence, ‘giv[ing] claims their broadest reasonable construction.’” *Belcher Pharm., LLC v. Hospira, Inc.*, 11 F.4th 1345, 1352 (Fed. Cir. 2021) (citation omitted). Elysium’s pleading does that.

Elysium both cites and attaches evidence that supports its factual assertion. D.I. 113 at Exs. 1-12. This is more than enough to meet the preponderance of the evidence standard, especially at the pleading stage when all inferences favor the non-movant.

Grace misapplies Elysium’s assertion that Grace’s pre-critical date NR-CI offers/sales create “a *prima facie* case of unpatentability” (D.I. 137 at 14), ignoring that Elysium first pleads it renders the claims invalid (D.I. 113 ¶73). *See id.* ¶76 (information “purposely was withheld from the USPTO in order to ... ***otherwise obtain claims that would not have been allowed.***”) As stated, *prima facie* unpatentability is a PTO tool to reject invalid claims – and that, as pleaded, shows “at a minimum” the but-for materiality of Grace’s hidden offers/sales. *Id.*; *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1334 (Fed. Cir. 2012) (“[E]ven if the

withheld reference is not sufficient to invalidate the claim in district court, [it] may be material if it would have blocked patent issuance under the PTO's different evidentiary standards.”).

C. Elysium Sufficiently Identified Specific Individuals Who Had the Requisite Knowledge and Deceptive Intent

Grace incorrectly asserts Elysium fails to meet the standards for materiality and intent set forth in *Exergen* because Elysium failed to plead that a specific individual (1) knew of the withheld material information and (2) withheld or misrepresented it with a specific intent to deceive the PTO. D.I. 137 at 16 (quoting *Exergen*, 575 F.3d at 1328-29). This is a misapplication of *Exergen* and a misreading of Elysium’s pleading.

In *Exergen*:

“the pleading refers generally to ‘Exergen, its agents **and/or** attorneys,’ but fails to name the specific individual associated with the filing or prosecution ... who both knew of the material information and deliberately withheld or misrepresented it. The pleading thus fails to identify the ‘who’ of the material omissions and misrepresentation.”

Id. at 1329 (citations omitted).⁵ In other words, that pleading was deficient because it did not name specific names, but instead used the company name and non-specific titles relying on the disjunctive “or” to avoid specificity. The “or”

⁵ *Exergen*’s Second and Third Rule 9(b) grounds are not applicable. That pleading failed to specify relevance or why information was not cumulative. *Id.* Elysium’s pleading, however, is clear as to the relevance of the hidden information.

allowed for mutually exclusive choices, and did not therefore identify the specific “who.” (Grace’s cites cases also criticizing the use of “or.” D.I. 137 at 18 (quoting from the *XpertUniverse* case).

Here, Elysium does not use “or,” simply say “Grace,” or rely on titles not identified with people. Elysium instead identifies specific individuals:⁶ the four inventors – primarily inventor Carlson but also Standen, Morrill, and Osuna – as well as Grace’s Reynolds, [REDACTED]. D.I. 113 ¶¶55-63, 68-69. There is no ambiguity as to *who* Elysium alleges is at issue.

Exergen is clear that intent does not need to be *proven* in a pleading, it can be averred generally so long as the facts used to infer intent are identified. 575 F.3d at 1328. The facts Elysium alleges (no depositions were taken when Elysium filed its amended pleading) show the most reasonable inference supports Elysium’s inequitable conduct counts: these seven were aware of and purposefully hid material information from the PTO to obtain allowance of claims that otherwise would have been rejected.⁷

⁶ Elysium’s pleading acknowledges that discovery might reveal others too, but this does not negate Elysium’s specifying individuals.

⁷ [REDACTED]

Rule 9(b) does not require a confession, sworn affidavit, declaration or direct proof of wrongful intent, as the *en banc Therasense* decision acknowledges (649 F.3d at 1290),⁸ *Exergen* makes clear (at 1328), and subsequent decisions applying *Exergen* elucidate.

In *Sanders v. Mosaic Co.*, for instance, Sanders failed to disclose a relationship with a declarant on Sanders' behalf. 418 F. App'x 914, 919 (Fed. Cir. 2011). Applying *Exergen*, the panel found the trial court properly allowed an inequitable conduct pleading, even though it did not "include any allegations of knowledge or specific intent to deceive"; it could reasonably infer knowledge and intent to deceive based upon the omission of publications co-authored by Sanders and the expert that were omitted from the expert's curriculum vitae submitted to the PTO. *Id.*

Similarly, in *Kaszuba v. Iancu*, the trademark complainant cited circumstantial evidence that Kaszuba told the PTO incorrect information and submitted "false specimens" "to fraudulently induce the USPTO to issue his use-based trademark registration." 823 F. App'x 973, 980 (Fed. Cir. 2020). The decision states that the pleading stage is "not concerned with whether [complainant] can prove its allegations of fraud and intent to deceive on the merits

⁸ Even *Therasense*, in its context, does not require direct proof of intent. 649 F.3d at 1290 ("Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence").

... we look to whether [complainant] has pled its fraud claim with particularity.”

Id. Accordingly, that pleading was sufficient under R.9.

Here, Elysium’s pleading contains the following factual allegation (among others):

- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]

[REDACTED]

The timing of these privileged communications creates a reasonable inference (if not outright proof) that the identified Grace employees engaged in the purposeful hiding of the invaliding offers/sales from the PTO. *Id.* ¶¶68-69. *See* 37 C.F.R. § 1.56 (Duty of candor extends to every “person who is substantively involved in ... prosecution[.]”); *Avid Identification Sys. v. Crystal Import Corp.*, 603 F.3d 967, 973 (Fed. Cir. 2010) (Executive substantively involved in prosecution committed inequitable conduct by withholding evidence of pre-critical date sales).

Consistent with the Federal Circuit’s *Therasense* decision *en banc*, *Exergen*, and cases such as *Sanders* and *Kaszuba*, these and the other recited facts support “a reasonable inference” that the individuals Elysium named intentionally withheld the on-sale bar evidence of patent invalidity in violation of their duty. *See Sanders*, 418 F. App’x at 919 (citing *Exergen*, 575 F.3d at 1328-29). At a minimum, it is a reasonable inference that they “knew of the purported offers or sales, knew that they were material, and withheld them with deceptive intent.” D.I. 137 at 18-19.

Grace argues Elysium has not pleaded facts specific to Mr. Carlson’s awareness of sales to ChromaDex, as senior scientist he would not know about sales (D.I. 137 at 19); Grace is wrong. Elysium did plead facts and attach exhibits

showing his awareness. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. Based on these facts alone, it is reasonable to infer that Mr. Carlson – and the other inventors – were well aware of Grace’s pre-critical date offers/sales of [REDACTED] NR-Cl.

Similarly, Grace argues that “Elysium pleads no facts tending to show that Mr. Reynolds” was aware of the alleged facts. *See* D.I. 137 at 19. Here again, Elysium alleged sufficient facts and attached exhibits that show the most reasonable inference is that Reynolds was aware of and knew the importance of the withheld information. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Elysium has met the pleading standard. *Targus Int'l LLC v. Victorinox Swiss Army, Inc.*, No. 20-464-RGA, 2020 U.S. Dist. LEXIS 232968, at *16 (D. Del. Dec. 10, 2020) (“In this district, an inequitable conduct claim is rarely disallowed at the pleading stage due to the failure to adequately allege scienter.”)

D. Elysium has Properly Pleaded that Grace Let Evidence Lapse

Finally, Grace alleges that Elysium failed to plead Grace “destroyed” evidence. D.I. 137 at 20. Again, Grace misstates Elysium’s pleading. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

At the pleading stage, Elysium is permitted to draw the reasonable inference based [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. *See also Genentech*, 2020 U.S. Dist. LEXIS 23311, at *7-8.

E. Elysium's Affirmative Defense Also Is Well Pleaded

As discussed, Elysium sufficiently pleaded its counterclaim for inequitable conduct. When a properly pled inequitable conduct claim is also an affirmative defense, the affirmative defense should not be stricken. *Southco*, 768 F.Supp.2d at 725. Accordingly, Plaintiff's motion to strike Elysium's corresponding affirmative defense should also be denied.

IV. CONCLUSION

For these reasons, Elysium's respectfully requests that the Court deny Grace's motion (D.I. 136).

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Dated: June 13, 2022

**CERTIFICATE OF COMPLIANCE
WITH TYPE VOLUME LIMITATIONS**

I certify that the foregoing brief satisfies the type volume limitations specified by Local Rule 7.1.3(4), as modified by Judge Colm F. Connolly's "Standing Order Regarding Briefing in All Cases." I certify that the text of this brief is presented in 14-point Times New Roman font and that, based upon the word count of the word-processing system used to prepare this brief, the number of words contained in the text of this brief is 4919.

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